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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,668	02/01/2000	Sergey A. Selifonov	3271.002US1	5158

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EXAMINER

KIM, YOUNG J

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/30/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/495,668	Applicant(s) SELIFONOV ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 May 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-30 and 45-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                               |                                                                             |
|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                              | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>20</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action responds the Amendment received on May 8, 2002 (Paper No. 22).

#### ***Information Disclosure Statement***

Applicants are reminded that the references cited in the IDS received by the Office on July 2, 2001 and August 11, 2001, were not hand delivered to the Examiner of record as indicated in the Applicants' remark (pp. 6) and therefore could not be considered.

#### ***Claim Rejections - 35 USC § 112***

The rejection of claims 5, 10, 14, 22, and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, in the Office Action mailed on December 31, 2001, is withdrawn in view of the claim amendment received on March 9, 2002.

#### ***Claim Rejections - 35 USC § 101***

The rejection of claims 1-30 under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility, in the Office Action mailed on December 31, 2001 is withdrawn in view of the arguments presented in the Amendment received on March 9, 2002 and in reconsideration.

#### ***Claim Rejections - 35 USC § 102***

The rejection of claims 1-5, 12-13, 14-17, 24-25, and 26-27 under 35 U.S.C. 102(a) as being anticipated by Sun (Journal of Computational Biology, 1999), in the Office Action mailed on December 31, 2001 is withdrawn in view of the claim amendment received on March 9, 2002.

#### ***Claim Rejections - 35 USC § 103***

The rejection of claims 1-30 under 35 U.S.C. 103(a) as being unpatentable over Sun (Journal of Computational Biology, 1999), in the Office Action mailed on December 31, 2001, is maintained for the reasons of record. The newly filed claims 45-56 is also rejected by Sun.

Applicants' arguments received on March 9, 2002 have been fully considered but they are not found persuasive.

Applicants argue that Sun reference does not teach or suggest the newly introduced limitation of, "making one or more product biological molecules corresponding to one or more product strings." This point is not found persuasive because Sun clearly discloses the motivation to conduct DNA shuffling:

"In DNA shuffling, one important objective is to obtain new DNA species by recombining mutations from the available different DNA species" (pp. 80, top).

Sun also suggest the clear motivation to conduct *in vitro* evolution, that is for producing, "molecules with desired properties" (Abstract), followed by their method of computerized DNA shuffling method, clearly envisioning to make the theoretical product into a physical product in order to realize the molecules with desired properties. Furthermore, Sun also compares their theoretically produced biomolecules with the biomolecules of the prior art (See Experimental Results section), envisioning making such biomolecules. Applicants also argue that Sun does not explicitly teach the selection of substrings, and concatenation of the substrings to form a product strings (pp. 9). Sun, however, discloses that their full length assembled molecules can be regarded as "concatenations of random fragments" (pp. 81). Sun, in fact disclose the selection of substring as well since a fragments of nucleic acid in computer environment (or substrings) are combined to form a product string (pp. 80). Finally Applicants argue that no support for "manipulating sequence strings and system" was found in Sun reference. Sun, however, disclose

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the probability of having mutations in the fragments which are being combined (pp. 83). Sun also discloses the results from comparing the experimental DNA shuffling to the theoretical model of DNA shuffling wherein the sequence being shuffled contained mutations (pp. 85, bottom) which indicates that the character string used in the theoretical model was “manipulated” to include mutations.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to use the knowledge that is within the purview of the artisan, such as homology determination, and combine them with the teachings of Sun to arrive at the invention as claimed to produce molecules with desired properties.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed; and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Inquiries***

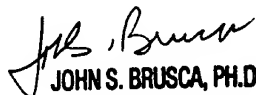
**Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348.**

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Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

7/29/02



JOHN S. BRUSCA, PH.D  
PRIMARY EXAMINER